K091736

510(k) Summary

Manufacturer Name: The Daniels Corporation PTY, LTD

Company Address: 135 S. LaSalle St, Ste 2850
Chicago, IL 60603

Representative

Andrea Arredondo
Daniels Sharpsmart, Inc.
2133-126 Upton Dr., #436
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OCT 30 2009

Summary Preparation Date: Sept 29, 2009

DEVICE NAME

Trade/Proprietary Name: Sharpsmart™ S2 disposable sharps container

Common Name: Disposable sharps disposal container

Classification Name: Accessory to hypodermic single lumen needle; Sharps Container

PREDICATE DEVICE IDENTIFICATION:

21CFR880.5570

Sharps Container

Product Code MMK

Device Class: II

LEGALLY MARKETED EQUIVALENT DEVICE:

Company	Product	510(k)#
Solutions, Inc	Sharps Away Disposable Container	K072667

DESCRIPTION OF DEVICE:

The Sharpsmart™ S2 disposable sharps container is intended to be used in patient rooms, medication rooms, operating rooms, physicians' offices or any other patient care area requiring the use of a sharps container. It is a two-piece injection-molded container made from a polypropylene copolymer. The container is designed with a closure mechanism that allows multiple lid re-openings, while ensuring secure closure between uses. Both handle and lid can be secured out of the way for safe, unobstructed disposal of sharps. The S2 container is capable of standalone use. A Unique bracket design is offered as an additional measure to secure mounting on vertical or horizontal surfaces to prevent toppling. The bracket is not required for the use of the container. It only offers a secondary option for the user for ease of use.

The containers are closable, puncture resistant, leak proof on the sides and bottom and stable. The label, containing an overfill warning and an easily visible fill line, is adhered to the container at the factory. The containers are translucent and are red or yellow. The label is white and red with the biohazard warning.

Sharpsmart™ S2 disposable sharps containers are available in a 1 quart size. Each product has two parts, which assemble together to form a unit. Assembly is easily visualized. They can be nested together to reduce storage space.

The container is designed and certified to comply with penetration requirements, as represented though product testing for Test methods: AS/NZS 4031:1992 and Test Method: UN Recommendations on the Transport of Dangerous Goods. 15th revised Ed. 6.1.5.3The Sharpsmart™ S2 disposable sharps containers meet or exceed OSHA recommendations for sharps containers.

INTENDED USE:
Sharpsmart™ S2 disposable sharps container are intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian office and other small quantity waste generators for the safe disposal of hazardous sharps. This device is intended for "Over-the-Counter" use.

S2 model is a 1 quart size. The container has a volume of 1.6quarts quarts, fill capacity of 1.16 quarts and an empty weight of 0.95 lb.

S2 model Color – Red with translucent lid or yellow with translucent lid.

S2 model outer dimensions of 7.50 "h x 4.50"w x 5.50 "d. (190mm x 115mm x 140mm).

PREDICATE PRODUCT COMPARISON TABLE:

Manufacturer	*Daniels Sharpsmart, Inc*	*Solutions, Inc*
Trade Name	Sharpsmart Disposable Sharps Container	Sharps Away Disposable Container
K Number	K091736	K072667
Indication for Use	Sharpsmart Disposable Containers are intended to be used for the safe disposal of hazardous sharps	Sharps Away Disposable Containers are intended to be used for the safe disposal of hazardous sharps
Target population	Healthcare professional	Healthcare professional
Where used	Healthcare facilities	Healthcare facilities
Material	Polypropylene	Polypropylene
Sharp Access	Sharps inserted through the top in a vertical position with sharp side down through a hole formed with flaps	Sharps inserted through the top in a vertical position with sharp side down through a hole formed with flaps
Sharps closure	Flaps are closed and locked in place for removal	Flaps are closed and locked in place for removal
Impact Resistance	Yes	Yes
Puncture Resistance	Yes	Yes
Leak Resistance	Yes	Yes
Single Use	Yes	Yes
Non-sterile	Yes	Yes

SUBSTANTIAL EQUIVALENCE DISCUSSION OF SIMILARITIES AND DIFFERENCES:

The Sharpsmart S2 Disposable Sharps Containers are similar to the Solution, Inc Sharps Away Disposable Containers in:

Non-Clinical test comparisons are viewed through: Intended Use, Materials and design.

Clinical tests are discussed in the Performance testing section.

Daniels submits the following information to demonstrate that the Sharpsmart S2 Disposable Sharps Container shares indications, design principles, materials and properties with the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices: Sharps Away Disposable Containers (K072667) from Solutions, Inc.

Intended Use Comparison

The indications for use of the Sharpsmart S2 Disposable Sharps Container are not new indications in that they are the same as or are included in those for the predicate devices. Sharpsmart and the predicate devices are containers intended to be used for the disposal of contaminated medical sharps in health care facilities.

Design and Materials Comparison

The design and functional characteristics of the Sharpsmart and the predicate devices are similar. They are constructed from polymeric materials. The Disposable Sharps Containers and Sharps Away containers are intended to be disposed once used. All of the devices conform to national or international standards for puncture resistance, impact resistance and leakage. They have means to prevent contact between the user and the contents, and are designed with features to easily and safely determine if they are full. They do not have features to bend, break or shear needles.

Performance Testing Comparison

Test methods: UN Recommendations on the Transport of Dangerous Goods. 15th revised Ed. 6.1.5.3; AS/NZS 4031:1992

Puncture Resistance –Passed	Handle Testing - Passed
Leak Resistance – Passed	Drop Test – Passed
Impact Testing – Passed	Stacking Test – Passed
Vibration – Passed	

Conclusion:

The Sharpsmart S2 Disposable Sharps Containers introduces no new questions concerning the safety or effectiveness of the Sharpsmart Disposable Sharps Containers and is thus substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Daniels Corporation PTY, Limited
C/O Ms. Andrea Arredondo
Compliance Manger
Daniels Sharpsmart, Incorporated
2133-126 Upton Drive, #436
Virginia Beach, Virginia 23454

OCT 30 2009

Re: K091736
Trade/Device Name: Sharpsmart™ S2 Disposable Sharps Contianer
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: October 2, 2009
Received: October 2, 2009

Dear Ms. Arredondo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRH Offices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): **K091736 -**

Device Name: **Sharpsmart™ S2 disposable sharps container**

Model: **S2**

Indications For Use: Sharpsmart™ S2 disposable sharps container are intended to be used in healthcare facilities, including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian office and other small quantity waste generators for the safe disposal of hazardous sharps. This device is intended for "Over-the-Counter" use.

Physical Attributes: S2 model is a 1 quart size. The container has a volume of 1.6quarts quarts, fill capacity of 1.16 quarts and an empty weight of 0.95 lb.

S2 model Color – Red with translucent lid or yellow with translucent lid.

S2 model outer dimensions of 7.50 "h x 4.50"w x 5.50 "d. (190mm x 115mm x 140mm).

Prescription Use _____ Over-The-Counter Use ____X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091736